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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/653,267	08/31/2000	Meir Eini	00/20309	4053

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04/26/2004

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BOSTON, MA 02109

EXAMINER

HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
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1616

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DATE MAILED: 04/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/653,267

Applicant(s)

EINI ET AL.

Examiner

Mina Haghighatian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37,40,41,43-51,104 and 105 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37, 40-41, 43-51, 104, 105 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of amendments filed 02/09/04. Now claims 37, 40-41, 43-51, 104 and 105 are pending.

OBJECTION

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 52 and 53 have been renumbered 104 and 105.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37, 40-41, 43-51, 104 and 105 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The added statement "wherein the composition is free of particulate material that prevents liquification of the carrier upon application of shear force" is not disclosed in the specification and is

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considered new matter. It appears that that the statement was inserted to distinguish the claim from prior art. The statement is also contradictory to the specification where additives such as colorants, dyes and pigments including salts can be added to the formulations.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 37, 40-41, 43-51, 104 and 105 are rejected under 35 U.S.C. 102(e) as being anticipated by Vatter et al (6,224,888).

Vatter teaches cosmetic compositions comprising from about 0 to 90% by weight of a solidifying agent, from about 0 to 90% by weight of an emollient component, from about 0 to 40% by weight of a polar solvent and from about 0.01 to about 50% by

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weight of vitamin B3 compound, thus meeting instant claims 37 (see abstract). The emollients of Vatter meet the hydrophobic solvent of the instant claims.

The suitable solvents include flavor oils such as peppermint oil, orange oil and citrus oil. Oils act as emollients and also impart viscosity, tackiness, and drag properties to cosmetic compositions such as lipstick. Examples of suitable oils include hydrogenated vegetable oils, castor oil, palm kernel oil, rapeseed oil, safflower oil, jojoba oil, avocado oil, evening primrose oil, etc (col. 5, lines 1-19; col. 6, lines 18-55; col. 12, lines 50-61).

Vatter describes the solidifying agents as being effective in solidifying the particular liquid base materials to be used in cosmetic compositions. The term "solidify" refers to physical and/or chemical alteration of the liquid base material so as to form a solid or semi-solid at ambient conditions. The solidifying agent is preferably present at a concentration of from about 0 to about 90%, more preferably from about 5 to about 40%. Suitable wax-like solidifying agents include fatty acids, fatty alcohols, fatty acid esters having fatty chains of from about 8 to about 30 carbon atoms. Preferred wax-like materials include cetyl alcohol, palmitic acid, stearyl alcohol, and mixtures thereof. Solidifying agents also include higher fatty acids, i.e. acids having from 12 to 22 carbon atoms. In the gel sticks the suitable solidifying agents are sodium and potassium salts of higher fatty acids, sodium stearate, sodium palmitate, aluminium stearate, etc. (col. 8, line 11 through col. 10, line 19).

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Vatter also teaches that the solidifying agent in combination with the emollient is believed to act as an occlusive on the skin by forming continuous or discontinuous bi-layer or multi-layer films on the skin (col. 10, lines 47-55).

Vatter discloses some optional ingredients suitable for the composition such as anti-inflammatory agents such as hydrocortisone, and other skin active agents such as vitamin D, retinoic acid, zinc oxide etc (col. 12, lines 19-49).

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37, 40-41, 43-51, 104 and 105 are rejected under 35 U.S.C. 102(b) as being anticipated by Xu (5,817, 322).

Xu teaches the preparation and struction of a pharmaceutical base comprising 5% to 25% by weight of beeswax and 95% to 75% by weight of a hydrophobic solvent (see abstract). The steps of preparing the pharmaceutical base are disclosed in detail in column 2, lines 53-64. xu discloses that such formulations are used for topical (external) use, to be applied on ulcerated skin, erosions, scarred skin, thermal injuries, wounds, etc (col. 4, lines 1-10). Xu discloses an example of an ointment preparation containing an active agent and sesame oil as the solvent (col. 4, example 2). In example 8, Xu discloses a formulation containing fluocinolone acetonide and sunflower seed oil. Other active agents disclosed include sulfadiazine silver for burns, clotrimazole for fungal infections, etc (see examples 1-9 and table 2).

Response to Arguments

Applicant's arguments filed 02.09/04 have been fully considered but they are not persuasive.

Applicant states that the compositions of the invention do not mention particulate additives and require only an appropriate proportion and composition of solidifying agent and hydrophobic solvent. Applicant also states that the solidifying agents of the present invention are not "particulate", as they dissolve in the hydrophobic solvent. However it is noted that the solidifying agents of the invention and the prior art are the same agents. The prior art and the invention, both recite additives a optional, and it is also noted that additives of the invention overlap with those listed in the prior art.

Applicant argues that Vatter discloses compositions with oil-insoluble powders such as titanium oxide and pigments. It is noted that these agents are listed as optional and are not required elements for the formulations. It is also noted that specification discloses adding the same additives (see pages 58-60).

Applicant argues that products disclosed by Vatter require a solid consistency and should not be flowable. This is not persuasive because Vatter is clearly disclosing that the products can be in a gel, mousse, foam or ointment. These forms are semi-solid in standing and liquefy upon application on skin.

Applicants arguments regarding the rejection of claims over Vatter in view of Geria (4,992,478) are moot since the said rejection is not maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mina Haghighatian
Patent Examiner
Art Unit 1616
April 22, 2004